

## **FDA News**

**FOR IMMEDIATE RELEASE**

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### **FDA Approves CustomVue Monovision LASIK**

The U.S. Food and Drug Administration approved for marketing the first LASIK device designed for treating one eye to see far away objects and the other eye for close-up vision.

“The approval of the CustomVue Monovision LASIK expands permanent vision correction options for nearsighted adults who also have trouble focusing on objects close-up,” said Daniel Schultz, M.D., director of FDA’s Center for Devices and Radiological Health. “Unlike traditional LASIK, Monovision LASIK may reduce the need for reading glasses in some people over 40.”

LASIK, or laser in-situ keratomileusis, is a procedure in which the surgeon cuts a flap in the outer layers of the cornea, removes a small amount of the tissue beneath it with the laser, and then replaces the flap. CustomVue Monovision LASIK produces monovision correction in nearsighted (myopic) adults, with or without astigmatism, ages 40 years or older with normal age-related loss of ability to focus on near objects (presbyopia).

The CustomVue device is designed to correct all nearsightedness in the patient’s dominant eye and only part of the nearsightedness in the non-dominant eye. This allows the patient to use the fully corrected eye for distance vision and the under-corrected eye for seeing close up. After a period of time, the brain adjusts to the difference in perception between the two eyes.

People considering CustomVue monovision LASIK should first wear monovision contact lenses for at least a week to determine if they can tolerate having one eye under-corrected. Following monovision surgery, the two eyes may not work together as well as they did before in some patients, especially in dim light or when performing tasks requiring very sharp vision or fine depth perception. Patients may need to wear glasses or contact lenses for some activities such as night driving or reading small type.

CustomVue Monovision LASIK is a permanent operation to the cornea. Side effects may include glare from bright lights, rings around lights (halos), light sensitivity, night driving glare, ghost images, double vision and visual fluctuation. CustomVue Monovision LASIK is manufactured by AMO/VISX Inc., based in Santa Clara, Calif. The new approval is for the monovision correction, which uses the previously approved wavefront-guided treatments—an eye-mapping system that guides the laser—for myopia and astigmatism. FDA based its approval on the review of a clinical study of safety and effectiveness outcomes submitted by the company.

At FDA’s request, AMO/VISX will conduct a post-approval study following 500 patients for six months after surgery to characterize quality of vision and quality of life issues associated with permanent LASIK monovision correction. The objective of the study is to estimate the proportion of monovision LASIK patients who experience visual disturbances that are severe enough to limit activities or adversely affect a patient’s quality of life.